REMARKS

This application has been reviewed in light of the Office Action dated January 23, 2009. Claims 1, 3 and 6-18 are presented for examination, of which Claim 1 is in independent form. Claims 1, 3 and 6-8 have been amended to better define the invention. Claims 4 and 5 have been cancelled. Favorable reconsideration is requested.

Claims 1, 3, 6, 7, 13 and 17 have been rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent No. 3,993,072 (Zaffroni). Claims 1, 3, 5, 13 and 16-18 been rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent No. 5,972,372 (Saleh et al). Claim 8 has been rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Zaffroni. Claims 1, 3, 6, 9-12, 14 and 15 have been rejected under 35 U.S.C. § 103(a) as allegedly being obvious over U.S. Patent No. 3,926,188 (Baker), in view of. U.S. Patent No. 2,962,023 (Chappaz et al.). Claims 1, 3, 6 and 13-15 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 4,217,898 (Theeuwes), in view of Zaffroni. Claim 4 has been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Zaffroni as applied to claim 1 above, in view of. U.S. Patent No. 3,924,622 (Brooke). Claims 5 and 8-12 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Theeuwes modified by Zaffroni as applied to claims 1 and 7 above, in further view of Chappaz. Applicants respectfully traverse these rejections, particularly in view of the amendments made herein.

Prior to discussing the merits of the rejections, Applicants believe it would be helpful to discuss the advantages of the device of this invention. As noted in the specification of the present invention, vaginal rings have been difficult to effectively use, particularly when a daily release rate of a drug on the order of milligrams per day is required, for delivering

hydrophilic or relatively large molecular weight (greater than 400 Daltons) drugs. See paragraphs 9-11 of the published application. It is respectfully submitted that the device of this invention, which overcome the aforementioned problem, is not disclosed or suggested by the art of record.

Zaffaroni concerns itself with a porous wall whose micropores contain a drug release rate controlling medium that is permeable to the passage of the drug at a rate that is lower than the rate of passage of the drug through the reservoir itself. Thus, the rate of passage of the drug through the pores is what is controlling the release of the drug from the device itself.

Zaffaroni teaches that drug release through this medium is controlled by controlling the relative size of the pores and the molecular radius of the drug molecule. At column 9, lines 39-54, it is taught that, when the radius of the pores is at least 10 times larger than the molecular radius of the drug molecule, there is no interaction between that wall material and the drug molecule. Further on, at column 10, lines 32-39, it is taught that pores sizes from about 10 angstroms to 100 microns can be suitably employed.

The Examiner has pointed to Examples 1, 16 and 18. Example 1 concerns a drug delivery implant device containing progesterone and having a microporous cellulose coating having pores with a diameter that permits the passage of steroids. The diffusion coefficient is $2x10^{-6}cm^2sec^{-1}$. Example 16 is directed to a T-shaped intrauterine device having a reservoir containing a pregestational or estrogenic antifertility steroid. The micropores are either charged with a diffusive liquid medium prior to uterine placement or are changed *in situ* with uterine biological fluid. Example 18 is directed to a vaginal ring having a microporous wall with micropores. The micropores can be pre-filled with diffusion medium or charged *in situ* with vaginal fluid.

It is clear that the micropores of Zaffaroni which are employed along with a permeable medium to control the rate of drug diffusion do not disclose or suggest a device having the holes or openings of the present invention, i.e., having a diameter in the range of 0.5 to 6.5 mm and the exposed claim recited surface area.

Saleh describes a vaginal ring having a hollow internal channel capable of receiving a drug-containing core. Salen discloses at page 3, lines 7-12, a sealant that may be used to separate the core from the exterior environment so as to prevent passage or diffusion of the drug from the core directly to the exterior environment. Further on, in discussing the Figure 4 preferred embodiment of the invention, the term "internal" is defined as meaning no portion of the core is exposed to, or in contact with, the outer surface of the ring body and vaginal ring is assembled and the opening is sealed (see column 6, lines 6-12). Further on, at column 6, lines 62-66, it is taught that the sealant closes the channel after core placement and minimises diffusion of the drug through the axial ends of the core. Claim 1 requires that no portion of the drug-containing core is exposed to the exterior of the vaginal ring body. In summary, although Saleh might suggest that an unsealed core could be made, it is respectfully submitted that no such embodiment is disclosed by Saleh. In fact since the whole point of Saleh is to control nausea and vomiting resulting from initial bursts of the drug, it is clear that Saleh does in fact teach away from the presently claimed invention. Therefore, it is respectfully submitted that Saleh does not anticipate or render obvious the presently claimed invention.

Baker suggests that certain drugs can be dispensed from a laminated dispenser comprising a drug-containing core partially covered with at least one rate-controlling outer lamina at an approximately constant rate, provided that there is a defined correlation between the

respective permeabilities, thicknesses and exposed surface areas of the core and the outer lamina(s).

The Baker device intends that the amount of drug directly released from the core is substantially less than the amount of drug released through the sheath and that this is how a substantially constant drug release rate is achieved (see, for example, column 3, lines 36-40). Column 4, lines 54-68 teach that the drug should have a low water solubility and that a water solubility of less than about 4%. Thus, Baker differs significantly from the presently claimed invention that provides substantial drug delivery from the core to the vaginal environment and is capable of delivering of relatively hydrophilic and/or large molecular weight products in milligram doses on a daily basis. It is respectfully submitted that Baker does not suggest such a device.

Chappaz has been relied upon to show that the Chappaz Figure 2 medicator is generally cylindrical and is intended for insertion into the vaginal cavity. However, this disclosure does not overcome the deficiency of Baker. Accordingly, the present claims are not rendered obvious by Baker in view of Chappaz.

Theeuwes is directed to osmotic devices and for that osmotic device to work in an aqueous environment, the reservoir must be hydrophilic. Thus, the replacement of the hydrophilic polymer with a hydrophobic elastomeric polymer, as is required by the present invention, is not an obvious design choice. In fact, despite reciting polyvinyl chloride as a hydrophobic elastomeric polymer, the Theeuwes invention will only work in an aqueous environment with hydrophilic polymers. There is nothing in Theeuwes that would have directed a person of ordinary skill in the art to the presently claimed device so as to overcome the

problems associated with the delivering relatively hydrophilic and large molecular weight drugs in milligram doses on a daily basis.

Brooke was relied upon by the Examiner for the disclosure of a slit. The claims have been amended to recite that the holes or openings are substantially circular. Thus Brookes in no longer relevant since it does not remedy the deficiencies of Theeuwes. Accordingly, the present claims are not rendered obvious by Theeuwes in view of Brooke.

In view of the foregoing amendments and remarks, Applicants respectfully request favorable reconsideration and early passage to issue of the present application.

Applicants' undersigned attorney may be reached in our New York Office by telephone at (212) 218-2100. All correspondence should continue to be directed to our address listed below.

Respectfully submitted,

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